



American Health Care Association

1201 L Street, NW, Washington, DC 20005-4046
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 2nd Main Fax: 202-842-3924
Writer's Telephone: 202-898-2858
Writer's E-Mail: byarwood@ahca.org
www.ahca.org

Robert Van Dyk
CHAIR
Van Dyk Health Care
Ridgewood, NJ

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VICE CHAIR
UHS-Pruitt Corporation
Norcross, GA

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IMMEDIATE PAST CHAIR
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Roanoke, VA

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Levering Management Inc
Mt Vernon, OH

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AT-LARGE MEMBER
Kennon S. Shea & Associates
El Cajon, CA

Wade Peterson
NOT FOR PROFIT MEMBER
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Mandan, ND

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NCAL MEMBER
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Wilsonville, OR

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ASHCAE MEMBER
Oregon Health Care Association
Portland, OR

Gail Radler
ASSOCIATE BUSINESS MEMBER
Care Perspectives
Phillipsburg, NJ

Bruce Yarwood
PRESIDENT & CEO

August 11, 2010

Via Electronic Mail

Dr. Donald Berwick, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Humber H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: File Code -2435-P
Department of Health & Human Services: Proposed Rule:
Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes,
75 Fed. Reg. 39641 (July 12, 2010)

Dear Dr. Berwick:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the Proposed Rule, "Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes," 75 Fed. Reg. 39641 (July 12, 2010) to implement Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) (Proposed Rule).

AHCA is the nation's leading long term care (LTC) organization representing more than 10,000 non-profit and proprietary facilities, which deliver the professional, compassionate, quality long term and post-acute care more than 1.5 million of America's seniors and people with disabilities rely on each day.

The majority of our member facilities participate as providers in the Medicare and Medicaid programs. As such, they are subject to annual and to complaint inspections and thus also subject to the various remedies that can be imposed as the result of survey findings, including a civil money penalty (CMP). AHCA and its membership have a direct interest to ensure a fair, prompt and workable survey and certification process that includes an impartial and efficient mechanism to resolve disputes regarding CMPs.

In drafting regulations to implement Section 6111 of the Patient Protection and Affordable Care Act, CMS has the opportunity to establish a speedy and fair mechanism to review the factual and legal basis for imposition of the CMP, to review the reasonableness of a CMP, and to secure expeditious collection of a CMP while other appeals are pending. While the Proposed Rule would likely accomplish early collection of CMPs, it would do so by distorting the letter and spirit of Section 6111. Instead of assuring independent review of a CMP before collection, the state survey agency whose surveyors provided the basis for the CMP would be authorized to conduct the review¹ and "user fees" would place the cost of independent review on the facilities

¹ See proposed §488.431(a)(5)(i) and (iii).

that request it, discouraging its use.² At the same time, the agency would defer to the State Operations Manual (that is not subject to rule making procedures) the “operational details” that could assure the fairness and efficiency of an independent review process.³

Section 6111 also provides for a reduction of civil money penalties when certain deficiencies are self-reported and corrected, but the Proposed Rule is not drafted to give nursing homes meaningful incentive to self-report. On the contrary, the self-disclosure provisions at proposed §488.438 would do little more than give CMS a road map to impose penalties that CMS does not presently have.

At its core, the Proposed Rule simply adds another layer to the existing unwieldy and complex enforcement system, creating new regulatory problems and ignoring the ones that already plague nursing homes: inconsistent application of professional standards among state surveyors; inconsistent and sometimes excessive penalty amounts across regions; and a tedious, slow and expensive administrative appeals process. As drafted, the Proposed Rule is an opportunity lost to improve care while increasing collaboration among nursing homes, survey agencies and CMS.

For the reasons set forth below, AHCA requests that CMS retract the Proposed Rule in its entirety and issue a new proposed rule that is consistent with and could achieve the potential of the underlying legislation.

Should CMS decide not to withdraw the Proposed Rule, we call your attention to the following concerns and ask that they be addressed in the final version of the regulation. The AHCA comments follow the order of the comments that accompany the Proposed Rule.

Section 6111 of the Patient Protection and Affordable Care Act

Section 6111 authorizes the collection of civil money penalties before appeal rights are exhausted or waived. Under prior law, in cases where the nursing facility had requested a hearing to contest the civil money penalty, penalties could not be collected until after a final administrative decision upholding the penalty. See 42 U.S.C. §§1395i-3(h)(2)(B)(ii); 1320a-7a(c)(2); 42 CFR §488.432. Subsection (a)(1)(B)(IV)(cc) now provides for the CMP to be collected and placed in an escrow account on the earlier of the date that an independent informal dispute resolution process is complete or 90 days after the imposition of the CMP and before a nursing facility has been afforded an opportunity for a hearing. While AHCA believes that the failure to provide a pre-deprivation hearing in this context violates well-established notions of fundamental fairness and due process of law, the absence of a pre-deprivation hearing also places significant emphasis on the importance of subsection (aa), under which the provider must have the opportunity to participate in a truly independent informal dispute resolution process not later than 30 days after imposition of the CMP. If the provider successfully

² See proposed §488.431(a)(4).

³ 75 Fed. Reg. 39646 (July 12, 2010).

appeals the penalty, the money placed in escrow is returned with interest. If not, some portion of the amounts collected may be used to support activities that benefit residents, including approved facility improvement initiatives.⁴

In addition, Section 6111 provides financial incentives for nursing homes to self-report and correct certain deficiencies. Under current law, the Secretary may impose a CMP in an amount not to exceed \$10,000 day for each day a nursing facility is not in substantial compliance with requirements for participation in the Medicare and Medicaid programs. 42 U.S.C. §1395i-3(h)(2)(B)(ii). Section 6111 amends the law to reduce CMPs by up to 50% if a facility self-reports and corrects a deficiency not later than 10 calendar days after imposition of the penalty. The reduction is not available for repeat deficiencies where a penalty had been reduced in the preceding year, or for deficiencies determined to constitute a pattern of harm or widespread harm, place the health or safety of a resident in immediate jeopardy, or result in the death of a resident. Essentially, the 50% reduction is available for penalties imposed on deficiencies generally regarded as less serious – those classified at a scope and severity level of “G” or less.⁵

The Proposed Rule

A. Proposed Rule: Proposed Establishment of an Escrow Account for Civil Money Penalties

Prior to enactment of Section 6111 the Department collected CMPs following exhaustion or waiver of hearing rights. 42 CFR §488.432. Section 6111 changes this, providing for collection of the civil money penalty in an escrow account on the earlier of the date on which the independent informal dispute resolution process is completed or 90 days after the imposition of the penalty. Section 6111(a)(1)(B)(IV)(cc).

In its comments accompanying the Proposed Rule, CMS supports the change asserting that facilities have been able “to avoid paying a civil money penalty for years.” 75 Fed.

⁴ In remarks from the floor of the U.S. House of Representatives on March 21, 2010, Congressman Henry Waxman stated that the purpose of Section 6111 was to make “collection of civil monetary penalties more timely” by allowing funds to be escrowed after an independent dispute resolution process until other appeals were concluded. 156 Cong. Rec. H1854-02 (2010 WL 1006359, p. 11).

⁵ Deficiencies are identified during standard surveys or complaint investigations and are classified according to their severity and scope. The severity levels - in increasing level of severity - are potential for minimal harm, potential for more than minimal harm, actual harm and immediate jeopardy. The scope of a deficiency is viewed in terms of whether it is isolated, reflects a pattern, or is widespread. The 12 classifications range in alphabetical order from the least serious “A” (isolated instance of no actual harm with potential for minimal harm) to the most serious “L” (immediate jeopardy to resident health or safety – widespread in scope). A “G” level deficiency is an isolated instance of actual harm that does not constitute immediate jeopardy to resident health or safety. GAO uses the term “serious deficiency” to refer to deficiencies at the level of actual harm or immediate jeopardy, i.e., deficiencies classified as a “G” or higher. GAO-07-241 (Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents), March 2007, p. 8. Deficiencies classified as “A,” “B,” or “C” level deficiencies are nevertheless deemed to reflect “substantial compliance” with Medicare requirements of participation.

Reg. 39643. Significantly, CMS does not state how many of the nursing homes that have been subject to CMPs in recent years actually embarked on the administrative appeals process.⁶ Nursing homes report that they do not pursue the administrative appeals process lightly as it involves expensive and lengthy briefing and hearing procedures, with outcomes that more often favor CMS than the facility⁷. There is thus reason to believe that the vast majority of nursing facilities pay CMPs promptly after receiving the notification from the CMS Regional Office, invoking their right to a 35% reduction under 42 CFR §488.436.

In the case of a per day penalty, subsection (a)(1)(B)(IV)(bb) of Section 6111 is explicit that “a penalty may not be imposed for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed.” (emphasis added) CMS ignores the underlined language, interpreting the legislation to mean that a per day penalty cannot be collected during the period between imposition of the penalty and the conclusion of the dispute resolution process, but it can continue to accrue and be collected thereafter. CMS defends this position on grounds of i) its “long standing position” that per day penalties accrue from the first day of non compliance until substantial compliance is achieved; ii) its view that Section 6111 “does not change the existing nursing home enforcement process” but simply adds an additional process; and iii) its belief that any interruption in accrual “would be contrary to the intended effect of creating financial incentives for facilities to maintain compliance and promptly correct any noncompliance.” 75 Fed Reg. 39644.

The CMS interpretation is directly contrary to the plain language of the statute which specifies that “a penalty may not be imposed for any day” during the period from the first day the CMP is imposed to the day on which the independent informal dispute resolution process is completed. None of the reasons CMS offers for its view is compelling nor supported in law. The goal of the survey and certification process is to verify or secure substantial compliance with federal requirements, not generate revenue. Secondly, long standing positions must yield to changes in the law. As to the third point, CMS reverses the incentives. For the vast majority of nursing homes, good care is good business.

⁶ CMS relies on two GAO reports for the proposition that payment of a CMP only after the decision was final “diminished the immediacy of the enforcement response;” insulated the facility from the repercussions of enforcement and undermined the sanction’s deterrent effect. 75 Fed. Reg. 39643. There is no basis for these sweeping assertions. The GAO reports evaluated only a limited numbers of facilities and in one conceded that its findings could not be generalized nationwide. See GAO-07-241 “Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents,” March 2007, pp. 3,4. Moreover, CMS itself selects the remedies it will apply and some do have immediate effect, such as denial of payment for new admissions. From a practical perspective, most facilities will “book” the penalty amount as a liability and will not have the money available to them as CMS implies. In any event nursing facilities do not control the duration of the administrative process or the delays in the rendering of administrative decisions, both of which lie within the purview of CMS itself.

⁷ The initial pre-hearing standing orders in the Civil Remedies Division typically require detailed pre-hearing briefing, preparation of affidavits for witness testimony, and detailed requirements for preparing exhibits. Post-hearing brief can follow in-person hearing. Non-federal parties are responsible for purchasing transcripts. The process is time-consuming and expensive.

Reasonable people can disagree as to whether the few financial incentives that Section 6111 affords - a potential 15% additional reduction for penalties imposed on lesser deficiencies and a suspension on all penalty accrual during the maximum 90-day period while independent dispute resolution is in process – are themselves sufficient to constitute a meaningful incentive for good care. CMS has no authority to render these minimal incentives smaller still. If anything, the interruption in accrual is incentive for CMS to provide for speedy independent review processes.

AHCA Recommendation:

Revise proposed §488.431 to conform to the plain language of Section 6111 and clarify that the CMP will not accrue during the period between imposition of the CMP and the conclusion of independent informal dispute resolution or 90 days from imposition of the penalty, whichever is earlier.

1. *Collection and Placement in Escrow Account*

CMS sets the CMP but acknowledges in its comments that informal dispute resolution may result in “adjustment” to the amount of the CMP. 75 Fed. Reg. 39644. The potential for adjustment is ignored in proposed §488.431 which emphasizes that CMS “retains ultimate authority for the survey findings and imposition of civil money penalties.” Nowhere in the proposed regulations does CMS provide guidance as to the weight it will accord the independent informal dispute resolution outcome or the grounds CMS may have to reject it.

If “independent” informal dispute resolution is to have any meaning, the regulations should identify the standard that must be met to demonstrate that a CMP is warranted or not excessive. In addition, the regulations should require CMS to state the factual basis for rejecting an independent informal dispute resolution favoring the provider. The former would be helpful to facilities determining whether to seek independent informal dispute resolution and would likely inform the content and conduct of dispute resolution thereby improving its efficiency. The latter would promote transparency in the process and assist the provider in determining whether there is a valid basis for or to pursue appeal.

Revise proposed §488.431 to specify that the standard to determine whether a CMP is warranted is whether there has been substantial compliance with the requirement of participation at issue.

Revise proposed §488.431 to specify that the factors to be utilized to determine whether a CMP is excessive are those set forth at 42 CFR §488.438(f) and the amount of the CMP that CMS has imposed for similar non-compliance across the regions.

Revise proposed §488.431 to identify the grounds upon which CMS may reject or modify independent informal dispute resolution determinations.

Revise proposed §488.431 to require CMS to articulate the factual and legal basis for rejecting or modifying independent informal dispute resolution determinations that favor the provider.

2. *When A Facility Is Successful In A Formal Administrative Appeal*

If an administrative law judge reverses a CMP, proposed §488.431(d)(2) would require escrowed amounts to continue to be held until a final Departmental Appeals Board (DAB) determination is made or CMS determines not to appeal. This is inconsistent with subsection (a)(1)(B)(IV)(ee) which states that in the case of a successful appeal, penalty amounts may be returned to the provider plus interest. There is no statutory requirement to wait for exhaustion of all administrative or judicial appeals and nursing homes are not accorded the same rights.

Nursing homes, like other businesses, need to be able to access available resources. In the event a CMP is reversed, nursing homes should be able to have use of their own funds. The requirement in proposed §488.431(d)(2) that funds remain in escrow until CMS decides to forego an appeal or the DAB affirms reversal of the CMP will place a disproportionate burden on smaller homes that do not have the cash reserves of larger operations. To avoid administrative burden, CMS could consider setting a reasonable threshold for return of the CMP: e.g., CMPs in excess of a \$100 shall be returned following CMP determinations reversed or reduced by an administrative law judge. In the event CMS prevails following final determination, the provider would be required to return the funds with interest for the applicable period.

AHCA Recommendation:

Revise proposed §488.431(d)(2) to provide for the return of escrowed funds to the provider if the administrative law judge reverses the CMP. A partial reversal would result in the return of a proportional amount of the escrowed funds.

Revised proposed §488.431(d)(2) to define “applicable interest” for both CMS and the provider to be the then current judgment rate of interest.

B. Proposed Reduction of a Civil Money Penalty by 50% for Self-Reporting and Prompt Correction of Noncompliance

Proposed 42 CFR §488.438 provides for a CMP to be decreased by 50% if a facility i) self-reports non-compliance before it is identified by a state surveyor or CMS or reported by a third party; ii) corrects the non-compliance within 10 days of its occurrence; and iii) waives its right to a hearing before an administrative law judge; as long as iv) the noncompliance did not constitute a pattern of harm, widespread harm, immediate jeopardy or result in the death of a resident; and v) the CMP is not imposed for a “repeat deficiency” (a deficiency in the same regulatory grouping of requirements found in the last survey).

The problems that arise from the proposed regulation are multiple and intractable. As drafted, a facility is eligible for the reduction if it has self-reported and corrected “non-

compliance" within 10 days of its occurrence. Once more CMS disregards the plain language of the Section 6111 which permits the available reduction to be claimed as long as the deficiency is corrected not later than 10 days after the penalty is imposed.

The Proposed Rule also ignores the fact that by law, all nursing homes have quality assessment and assurance committees in place to identify potential quality issues and to develop and implement appropriate plans of action to correct them. The records of such committees are protected; and neither the Secretary nor a State may require disclosure of the records of such committee except for demonstrating compliance that such committee is in place. 42 U.S.C. §1395i-3(b)(1)(B). The Proposed Rule neither acknowledges the existence of such committees or provides protection for quality assurance records that may relate to issues facilities choose to report in order to obtain the available reduction.

Similarly, the Proposed Rule does not recognize that the PPACA requires all facilities to have Compliance programs and Quality Assurance and Performance Improvement programs within thirty-six months of enactment. See Section 6102. These new programs are expected to emphasize the importance of a facility using a robust compliance and facility improvement program to achieve and maintain compliance. Intrinsic to these two types of programs is to regularly review facility activities and patient outcomes; identify areas of concern (and potentially issues that could be considered a deficiency); and develop and implement a plan to correct these areas of concern. Nothing in the Proposed Rule prevents CMS from obtaining the records or self-critical analysis arising from the implementation of a nursing home's compliance program or Quality Improvement and Performance Improvement program and using this information to increase penalty amounts or the level of a deficiency, thereby disqualifying it from seeking a reduction.

More complicated is the failure of the proposed §488.438 to encourage self-reporting at all. Deficiency is a defined term and means a nursing facility's failure to meet a requirement for participation. 42 CFR §488.301. "Noncompliance" is also a defined term and means any deficiency that would cause a facility to be not in substantial compliance, i.e., deficiencies that are classified at a "D" level or higher. *Id.* By its terms, Section 6111 offers nursing homes a financial incentive to report noncompliance that could be classified at a deficiency level of "D," "E," "F," or "G." There is nothing, however, that guides nursing homes as to whether a self-report of noncompliance that it believes to be at those levels will result in the facility actually qualifying for the incentive.

Indeed, were a facility to self-report, the information reported could be used to the detriment of the facility. There are wide variations in fact patterns that constitute deficiencies and significant differences in the range of penalties assessed for specific deficiencies.⁸ If CMS unexpectedly classified facts reported as "immediate jeopardy" or a pattern or widespread actual harm, the facility would be in the unfortunate position of having "by the facility's own admission, through its self-reporting and

⁸ CMS and GAO have acknowledges the inconsistency in how states conduct surveys. GAO -07-241, pp. 20. Moreover, AHCA has reported to the CMS Central Office on many occasions the differences in the range of penalties among regions.

correction...acknowledged its noncompliance.” For CMS this is an easy roadmap to penalties. It also “substantially ...[eliminates] the basis for any formal appeal.” 75 Fed. Reg. 39645.

Under proposed §448.438(c)(2)(i), a facility only qualifies for the reduction if the noncompliance is reported before CMS or the State identify the noncompliance or before a complaint is made by a third party. In many cases there is a lag between the time of the survey and the time a specific fact pattern is identified as a deficiency. In addition, a facility often will not know that a complaint has been made. At a minimum, the facility should be given credit for self-reporting if it does not have affirmative knowledge that noncompliance has been identified by or reported to CMS.

The proposed regulations also do not address how CMS will determine whether a self-reported deficiency has been “corrected.” Generally, a facility will identify the improvements needed following notice of adverse survey findings in a “plan of correction” that is filed within 10 days of receipt of the CMS form 2567 Under §488.430 CMPs may be imposed for past noncompliance, but a plan of correction is not required . See State Operations Manual, 100-07, §7304D (Rev. 1,05-21-04). If eligibility for the 50% penalty reduction requires proof that self-reported deficiencies have been corrected, CMS should advise how a facility can demonstrate correction or how CMS will confirm that it has occurred.

One problem with the current survey and certification system is that non-compliance is often a product of an individual surveyor’s point of view. For example, a facility could self-report that a resident with dementia went out the facility’s front doors without authorization and was immediately brought back inside without having incurred any harm. The facility could reasonably conclude that these events constituted noncompliance with the resident’s care plan, would be viewed as a “D” level violation, and that correction was effected by conducting a root cause analysis, determining that the resident was “leaving for work” in his or her view, and the resident’s care plan was updated to include the resident in the facility’s “wander risk residents”. Appropriate changes would then be made to the resident’s care plan. Weeks or months later, a survey team conducting an annual or complaint survey could infer from the same set of facts that the situation constituted elopement, that the problem had not been corrected because the real problem was with the facility’s electronic monitoring system and that all residents suffering dementia were therefore in immediate jeopardy. Under such a scenario, the facility would have conceded non-compliance, the period of non-compliance would not have ended, and the facility would be exposed to a penalty of \$3050 to \$10,000 per day for which the 50% reduction is unavailable. Moreover, CMS could argue that there was no basis for appeal as non-compliance had been admitted.

Under 42 CFR §488.436 a facility is entitled to a 35% reduction of any CMP if it waives its right to appeal the penalty. The proposed regulation provides that the 50% reduction cannot be in addition to the existing 35% hearing waiver reduction, as the facility is only entitled to one option. We note that there is nothing in the statute that would preclude a facility from receiving both reductions. For a facility that would rather take a reduction in penalty amount than pursue an administrative appeal the difference between the 35% hearing waiver reduction and the more limited 50% reduction may not be worth the risk

of admitting noncompliance and inviting scrutiny. Under the proposed regulations and its accompanying guidance, the primary beneficiary of the self-report is CMS which will have a new way to find deficiencies (and impose CMPs).

AHCA Recommendation:

Revise proposed §488.438 to define “self-report” to mean a voluntary written report to the state survey agency that the facility has identified and corrected potential non-compliance with a requirement for participation.

Revise proposed §488.438 to clarify that a self-report and correction will i) not be deemed an admission of noncompliance for any purpose other than asserting a right to the 50% reduction in CMP; ii) not be a basis for increasing a CMP amount or changing a deficiency level to a higher level; iii) not be used against a facility in an otherwise valid appeal; and iv) not constitute a waiver of any quality assurance or other legal privilege.

Revise proposed §488.438 to conform to the plain language of Section 6111 and clarify that the available reduction will occur as long as the deficiency is corrected not later than 10 days after imposition of the penalty.

Revise proposed §488.438 to clarify how CMS will establish that past noncompliance has been corrected. In this regard AHCA urges CMS to recognize that past noncompliance has been deemed corrected if noncompliance is not present at the time of the survey.

Revise proposed §488.438(c)(2) to provide that a self-report and the associated 50% reduction in CMP will be accepted as long as the facility does not have actual knowledge that CMS or the State have identified noncompliance or that a third party has reported noncompliance.

Revise proposed §488.431 to provide for a facility to receive both the 35% and 50% reductions.

C. Proposed Rule: Establishment of an Independent Informal Dispute Resolution Process

Section 6111 at Subsection IV(aa) provides for a facility to have an opportunity for independent informal dispute resolution if a CMP is imposed. The process must be offered not later than 30 days after imposition of the CMP and generate a written record before the penalty is collected. The focus of the subsection is the “independent” review and the term is not qualified or limited in any way. Clearly, Section 6111 offers an important protection when CMPs – some of which can range in the hundreds of thousands of dollars – are to be collected before available appeal rights are exhausted.

Under proposed §488.431(a)(5), however, the independent informal dispute resolution process would be conducted by a CMS approved entity, including a state agency “which has no conflict of interest.” Under proposed subsection (a)(5)(iii) this could include a

“distinct part” of the state survey agency itself “so long as the individuals conducting the independent informal dispute resolution have no conflict of interest and have not directly participated in the survey that is the subject of the dispute resolution process.”

Subsection (a)(5)(i) would permit a component part of an umbrella state agency that is organizationally separate from the survey agency to conduct the review.

Under proposed §488.431(a)(4), a decision to seek “independent” informal dispute resolution would be at the facility’s expense, using a fee system “designed to cover... actual expenses...based on average costs.” The fee would be returned only if the CMP is completely eliminated.

Collectively, these proposed regulations satisfy neither the letter nor spirit of Section 6111. First, proposed §431(a)(5) would expressly permit the dispute resolution to be conducted by the same survey agency that provided the basis for imposition of the CMP and that is charged with interpreting requirements for participation. This sets up an inherent conflict of interest that cannot be resolved merely by eliminating from participation in the process the individuals who “directly participated” in the survey that gave rise to the CMP or who otherwise have a conflict of interest. As a general proposition, state survey agencies are an often cohesive group whose members know one another, where priorities are known and shared, and where some level of loyalty may be reasonably assumed. Words have meaning. A truly “independent” process can only be achieved where dispute resolution is conducted by an entity and persons without interest in the outcome.

Secondly, by charging a nursing facility for the actual costs of an independent review, but not the regular dispute resolution process under §488.331, CMS blatantly discourages independent review in favor of the usual – and by inference not independent - review process. Significantly, CMS does not specify its authority for imposing a user fee. CMS merely notes that the nursing home “is free to make a market place decision as to whether the user fee will be worth the cost compared to the option of using the current informal dispute resolution process that involves no user fee for the facility.”⁹ CMS could not signal its disdain for the independent review process more loudly.

Under proposed §488.431(a)(4), CMS would reimburse the fee charged only in the event that the applicable civil money penalty is completely eliminated. Reduction of a CMP following informal dispute resolution reflects at least partial vindication for the nursing home. A fee arrangement that makes a nursing home pay for any part of the state survey agency’s error is simply unfair. The bottom line, however, is that nursing homes seeking to challenge a CMP they believe to be unfair or improper should not have to pay for the opportunity to assert their rights, where, as here, the enabling legislation did not require this.

As well, proposed §488.431(a)(3), CMS requires that the independent informal dispute resolution process include notification to an involved resident or a resident representative, as well as the state ombudsman, with respect to the opportunity to provide written

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75 Fed. Reg. 39647.

comment. This provision is not supported by Section 6111 and we disagree with the required notification prior to an independent informal dispute resolution.

Finally, the Proposed Rule does not clarify whether the independent informal dispute resolution is in addition to or in lieu of the regular IDR process where utilized. Many states have effective informal dispute resolution programs. A nursing home should be able to pursue either or both.

AHCA Recommendations:

Revise proposed 42 CFR §488.431 to require that the entity or persons conducting informal dispute resolution be organizationally separate from the state survey agency.

Revise proposed 42 CFR §488.431 to eliminate the provisions for user fees.

Revise proposed 42 CFR §488.431 to eliminate the required notification to an involved resident or a resident representative, as well as the state ombudsman, with respect to the opportunity to provide written comment.

Revise proposed 42 CFR §488.431 to clarify that a nursing facility may use both the regular and informal dispute resolution processes should it so choose.

D. Proposed Acceptable Uses of CMPs Collected by CMS

Section 6111 at subsection (a)(1)(B)(IV)(ff) expressly authorizes CMS to use some portion of the CMP collected “to support activities that benefit residents.” The statute gives CMS broad discretion here, but suggests many examples, including “projects that support resident and family councils” and “facility improvement initiatives” (emphasis added). The legislation provides CMS with a unique opportunity to reach out to nursing homes and direct that penalty money be used in a way to improve care for their residents. Perhaps the most disappointing aspect of the proposed regulations is that they do nothing to expand on a concept that could benefit all parties involved.

In the last years the survey and certification system has developed into a distressing “gotcha” game where often overworked and understaffed surveyors are sent to inspect nursing homes and resident records to find “deficiencies” based on “guidance” published in the State Operations Manual. Whether or not a deficiency is found or a CMP will be imposed can vary with the individual surveyor, the survey agency or the CMS regional office to which the surveyor agency reports. Scope and severity assessments can also differ radically: what one surveyor may interpret as a level “D” deficiency (isolated and no actual harm), a regional office can view as a “J” (isolated immediate jeopardy). CMP amounts vary across CMS regions and can greatly exceed the amount recommended by the state survey agency. In addition, when deficiencies are found there can be long lapses of time before a survey agency performs a revisit survey.

In directing that some portion of the CMP amounts may be used to support activities that benefit residents as well as for facility improvement initiatives Section 6111 reminds that one critical aspect of the PPACA was to give the regulatory agencies the ability to try different ways to enhance quality of care. By its terms, Section 6111 injects potential for collaboration in the complex and often adversarial nursing home enforcement system. AHCA agrees with the use of CMP amounts for joint training of facility staff and surveyors.

There are multiple ways in which CMS could promote efforts to encourage states and facilities to develop innovative and cost-effective efforts to improve the operation and maintenance of facilities, protect residents and improve quality of life. Using Wisconsin as an example, CMS could establish a committee, perhaps composed of both regulators and providers, to review proposals and distribute CMP funds to providers or others who demonstrate innovative projects designed to protect the health, safety, and welfare of residents in a facility, or to improve the efficiency and cost effectiveness of the operation of a facility so as to improve the quality of life, care, and treatment of its residents. See, e.g. Wis. Admin Code DHS 132.16.

CMS could also direct that a portion of CMP funds collected from a facility be used to secure technical assistance for that facility so that its quality assurance methods are improved, as identified in the proposed regulation. Still other options include using funds for joint surveyor and provider training on aspects of the nursing home regulations or for direct care purposes. In Indiana, for example, CMP funds have been used to purchase pressure mattresses for each Indiana facility with the goal of decreasing pressure ulcers and staging leadership conferences that focus on specific long term care regulatory issues. See e.g., IC 16-28-12-2(d). There are an infinite number of ways that CMP money could be utilized to improve quality in nursing homes. The proposed regulations suggest no such potential, missing an opportunity for enlightened enforcement.

Finally, AHCA does not agree with the commentary regarding the regulatory impact of the rule in that the rule does have potential economic impact requiring compliance under Executive Order 12866 as well as significant impact on the operations of a substantial number of small rural businesses requiring compliance with section 1102(b) of the Social Security Act. AHCA requests that CMS elaborate on the bases for its assessment that the rule does not require these regulatory impact analyses.

Again, AHCA requests that CMS retract the Proposed Rule in its entirety and issue a new proposed rule that is consistent with and could achieve the potential of the underlying legislation.

AHCA appreciates the opportunity to present these comments to the Department. We hope the information presented will be useful to the Department in revisiting the policies set forth in the Proposed Rule and developing regulations that are faithful to the legislation and fair to the provider community.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce Yarwood". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Bruce Yarwood
President & CEO